ISRCTN12640591 https://doi.org/10.1186/ISRCTN12640591

Testing a diabetes ketoacidosis simulation teaching intervention in critical care nursing

Submission date
25/05/2019

Recruitment status
No longer recruiting

Registration date
13/06/2019

Overall study status
Completed

Last Edited
30/03/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nursing students are trained to acquire the capabilities to integrate cognitive, conative, and psychomotor competency skills. Students have fewer opportunities to experience diabetes ketoacidosis, so it is challenging for them to provide patient care. Simulation is one of the innovative teaching and learning practices to provide a realistic experience of diabetes ketoacidosis for student nurses. A wide variety of simulated patient care experiences can be provided in a high-fidelity simulation for critical thinking and self-confidence. With an increasing number of student nurses and the lack of clinical placement opportunities in the Middle East, use of simulation as a teaching-learning nexus pedagogy can help students to develop and master core competencies and achieve high standards of practice.

The aim of the study was to evaluate the effectiveness of simulation teaching intervention for diabetes ketoacidosis in critical care nursing in a public university. The findings may assist to design best educational practices in improving simulation experiences in the nursing program.

Who can participate?
Nursing students at Sultan Qaboos University registered in CCN section A and CCN section B in the Fall 2015 and Spring 2016 can take part.

What does the study involve?
The critical care nursing course developed the high-fidelity simulation presented for diabetes ketoacidosis (HFS-DKA) to integrate cognitive and psychomotor skills of diabetes ketoacidosis that reflected on the learning outcomes. The HFS events and cues that would trigger problem identification, nursing assessment, starting actions/interventions and prioritizing nursing care using a problem-solving approach was developed to run for 30-minutes. Each student was informed with the study information package, signed the confidentiality agreement and consent release form to maintain integrity and concealment of the HFS. The control group participated in standard YouTube videos guided by the teacher portraying cognitive and psychomotor skills for learning about diabetes ketoacidosis on assessment/ physical examination, intravenous fluid, electrolyte and insulin administration, monitoring nutrition and blood glucose.
The study information outlined important information to help you decide whether or not you would like to take part in this research. If you agree, we will ask you to take part in a survey and a

potential simulation teaching intervention. We will ask you to share information about yourself and learning. The audio recording of the simulation will be private, and your name will not be used in this study. The tapes of the simulation will only be seen by the research assistant and coordinator. The tapes and surveys will be kept in secure storage following the research. The survey in professional journals will appear for teaching and research purposes without any identification.

What are the possible benefits and risks of participating?
Participation might benefit individuals directly, but the information will help the teaching faculty in the nursing curriculum and program to design simulation intervention.
It is not expected that taking part in this study would cause any harm.

Where is the study run from?
Sultan Qaboos University, Oman.

When is the study starting and how long is it expected to run for?
September 2015 for one month.

Who is funding the study?
Sultan Qaboos University, Oman.

Who is the main contact?
Dr Melba D'Souza,
desouzamelba123@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Melba D'Souza

ORCID ID
https://orcid.org/0000-0002-3156-0663

Contact details
College of Nursing
Sultan Qaboos University
Muscat
Oman
123
1-604 751 6672
mdsouza@tru.ca

Additional identifiers

Protocol serial number
IG/SQU/CN/AHCC/15/7/21

Study information

Scientific Title
Testing a high-fidelity simulation- diabetes ketoacidosis teaching intervention in critical care nursing: a randomized control trial

Acronym
HFS-DKA

Study objectives
A high-fidelity simulation-diabetes ketoacidosis teaching intervention improves satisfaction, self-confidence, critical thinking and critical thinking disposition compared to learning from YouTube in critical care nursing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2015, Sultan Qaboos University institution ethics board (Mr Ramesh Venkatesaperumal, Assistant Dean Undergraduate Studies, Sultan Qaboos University, sageorgelav@gmail.com; 968 - 98137770) ref: IG/SQU/CN/AHCC/15/7/21

Primary study design
Interventional

Study design
Two arm randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
High-fidelity clinical simulation in nursing education

Interventions
The critical care nursing (CCN) course team created the high-fidelity simulation presented for diabetes ketoacidosis (HFS-DKA) scenarios using the high-fidelity simulator Lardeal SIM man. The HFS-DKA scenario was developed to integrate cognitive and psychomotor skills of diabetes ketoacidosis that reflected on the learning outcomes. The HFS events and cues that would trigger problem identification, nursing assessment, starting actions/interventions and prioritizing nursing care using a problem-solving approach was developed to run for 30-minutes. One hour was assigned for pre-briefing using case studies to share conversations. After the simulation activities were completed, a debriefing was performed for one hour by the qualified clinical teachers.

The clinical teacher provided the patient and physician voice. The laboratory technician operated the inputs and parameters of the computerized HFS. The validity of the HFS-DKA scenario was verified by a certified diabetes nurse educator, a registered nurse, a nursing faculty, and a

physician, based on a rating scale strongly agree to strongly disagree with open-ended questions. The validity and appropriateness of the high-fidelity simulation scenarios reflected the learning outcomes.

At the baseline/pre-test, the student completed a demographic profile, SSSCL, SDS, EPQ, CCTDI and CCTST surveys.
• Student Satisfaction and Self Confidence in Learning (SSSCL)
• Simulation Design Scale (SDS)
• Educational Practice Questionnaire (EPQ)
• California Critical Thinking Disposition Inventory (CCTDI)
• California Critical Thinking Skill Test (CCTST)

In the simulation group, there were 10 independent groups of 4 students in each group who were exposed to the complete HFS-DKA for 3 hours respectively. Each student group entered the simulation room and was given a script of the case scenario, background and clinical information and vital signs were displayed on the bedside monitor. A total of 30 hours of HFS was performed over 4 days for the simulation group in the third week of the CCN course in the Fall 2015 and Spring 2016 semesters Each student was informed with the study information package, signed the confidentiality agreement and consent release form to maintain integrity and concealment of the HFS. The control group participated in standard YouTube videos (60 minutes) guided by the teacher portraying cognitive and psychomotor skills for learning about diabetes ketoacidosis on assessment/ physical examination, intravenous fluid, electrolyte and insulin administration, monitoring nutrition and blood glucose. The students were not exposed to the HFS and debriefing.

The students who volunteered to participate in the study were confidentially assigned to the simulation or control group using the randomization in a permuted block for a block size of 4 using equal numbers to each treatment. Block 1 randomizes 4 students, with the first two assigned to simulation and the last two assigned to control group. The target sample size is 164 students (82 in Fall 2015 and 82 in Spring 2016) and the investigators enrolled 16 students each week. Each week the students were assigned a simulation and control group on a randomly assigned block specified for the week. Eighty-two students were registered in each CCN course section A (n=41) and B (n=41) in Fall 2015 and 82 students were registered in each course section A (n=41) and B (n=41) in Spring 2016.

The critical care nursing course developed the high-fidelity simulation presented for diabetes ketoacidosis (HFS-DKA) to integrate cognitive and psychomotor skills of diabetes ketoacidosis that reflected on the learning outcomes. The HFS events and cues that would trigger problem identification, nursing assessment, starting actions/interventions and prioritizing nursing care using a problem-solving approach was developed to run for 30-minutes. One hour was assigned for pre-briefing using case studies to share conversations. After the simulation activities were completed, a debriefing was performed for one hour by the qualified clinical teachers. In the simulation group, there were 10 independent groups of 4 students in each group who were exposed to the complete HFS-DKA for 3 hours respectively.

Intervention Type
Behavioural

Primary outcome(s)
1. Satisfaction and confidence measured using Student Satisfaction and Self Confidence in Learning (SSSCL) at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).

2. Self-confidence measured using Simulation Design Scale (SDS) at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).
3. Education practice measured using Educational Practice Questionnaire (EPQ) at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).
4. Critical thinking disposition measured using California Critical Thinking Disposition Inventory (CCTDI) at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).
5. Critical thinking skills measured using California Critical Thinking Skill Test (CCTST) at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).

Key secondary outcome(s)
1. Knowledge score measured by examination at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).
2. Skill performance measured by examination at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).
3. Objective structured clinical examination (OSCE) measured by examination at baseline, pretest (week 4), intervention (weeks 6-10), post-test (week 12).

Completion date
30/05/2016

Eligibility

Key inclusion criteria
1. Students registered in CCN section A and CCN section B in the Fall 2015 and Spring 2016
2. Willing to participate in the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
164

Key exclusion criteria
Do not meet inclusion criteria

Date of first enrolment
01/09/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Oman

Study participating centre
Sultan Qaboos University
College of Nursing, Sultan Qaboos University
Al-Khoud
Muscat
Oman
123

Sponsor information

Organisation
Sultan Qaboos University

ROR
https://ror.org/049xx5c95

Funder(s)

Funder type
University/education

Funder Name
Sultan Qaboos University

Alternative Name(s)
SQU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Oman

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality and anonymity from the written consent signed by the participants in the public university, confidentiality agreement form signed with the institutional board ethics and maintaining the identity and the concealment of the participants and the school of nursing.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	30/03/2020	Yes	No
Participant information sheet	Participant information sheet	04/06/2015	14/06/2019	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes